

of the support structure 11 using the same or an other suitable attachment means 30. The valve structure 12 is configured so that it advantageously expands with the deployment of the proximal and distal sections 15,17 such that the outer edges ~~37~~ 39 thereof contact the vessel wall sufficiently to at least substantially prevent leakage of bodily fluid around the valve structure 12. Optionally, the wall-engaging outer edges of the leaflets 26 can be reinforced with a separate frame 32 that is attached to or incorporated into the outer edges 39 to improve sealing with the vessel wall 38. An example of such a frame 32 is depicted in embodiment shown in FIG. 3 in which the frame 32 also serves as the interconnecting means 36 between the proximal and distal section 15,17 of the support structure 11, with the struts 18,19 being laser cut from the same tube used to form the remainder of the support structure 11. The valve frame 32 (that portion of the support structure 11 that reinforces the valve structure 12) can either be configured to exert relatively little radial force beyond what might be required to ensure adequate contact with the vessel wall 38, or it may be configured such that the frame 32 exerts sufficient radial force such that it assists in creating an artificial sinus 34 in the portion of the vein along the intermediate section 16 of the valve prosthesis 10.

--

Page 17, paragraph beginning on line 1, amend to read:

-- FIGs. 9,11, and 13-20 comprise embodiments of an artificial valve prosthesis 10 in which support structure 11 carrying the leaflets 26 is configured to increase the leaflet contact (coaptable) area 57 about the proximal portion of the valve structure 12 without relying on built-in slack within the material to bring the leaflets in closer proximity and provide for a extensive sealing area, longitudinally. As defined in this application, the leaflet contact area 57 comprises a longitudinal portion along the valve structure 12 in which the facing surfaces of opposing leaflets 26 (two or more) coapt or lie in close proximity to one other while in a dry or resting, neutral state (i.e., the pressure differentials across the valve orifice are essentially equalized such that the leaflets are not being forced together or apart due to external forces, such as fluid flow), when the prosthesis is an expanded or deployed configuration. The support frame 11 may be configured for maximizing the extent of the leaflet contact area 57 by including one or more longitudinal attachment struts 49,50 that define at least the proximal portion 75 of the attachment pathway 74 of each leaflet lateral outer edge 87,88 (the terms outer edge 39 and lateral outer edges 87,88 being defined herein as the

area or zone along the leaflet that comprises the sealing interface). The longitudinal attachment struts 49,50/proximal attachment pathways 75 have a substantially longitudinal orientation (e.g., substantially parallel) with respect to the longitudinal axis 64 of the prosthesis (and valve structure 12). At a point generally proximate the distal end 89 of the leaflet contact area 57 (the proximal portion 96 97 of the leaflet), the distal portions 76 of the adjacent attachment pathways 74 (which are joined proximally about a commissural point) diverge from one another (forming a generally Y-shaped pathway configuration) and assume a much more circumferential orientation than that of the proximal portion 75 of the pathway such that the outer leaflet lateral edges 87,88 of each leaflet converge at a point lateral to the free inner edge 84 thereof to seal the passageway and form the distal portion 96 of the leaflet that defines the bottom 96 or 'floor' of the pocket 55 35 or intravascular space adjacent the outer surfaces of each of the leaflets, which generally assumes a strongly cupped or curved shape such that the leaflet assumes a generally 'folded' appearance due to the acutely angled attachment pathway 74 with the proximal portion of the leaflet having a strong longitudinal orientation with respect to the prosthesis and vessel and the bottom portion 96 having a strongly perpendicular orientation relative to the longitudinal axis of the vessel and prosthesis. It should be noted that the commissures 27,28, while located about the proximal end 13 of the illustrative prosthesis 10, may be located proximal thereto such that additional support structure 10 extends proximally, such as in the embodiments of FIGs. 2-8,12.

Page 20, paragraph beginning on line 23, amend to read:

- - The embodiment depicted in FIGs. 13-14 comprises a pair of longitudinal attachment struts 49,50, generally parallel to one another, which are adapted for attaching the respective leaflets 26 60,61 therealong, thus creating a large leaflet contact or coaptable area 57 that extends over half of the length of the prosthesis. As depicted in FIG. 16, The lateral support structure 53,54 shares or mirrors the configuration of the longitudinal attachment strut regions which they interconnect, except that they are located 90° therefrom and oriented oppositely thereto, such that the support structure 11 generally forms a serpentine configuration adapted to be readily collapsible and expandable. In the illustrative embodiment, the support structure 11 or frame can be divided into four sections or quadrants 70,71,72,73 that are identical except for their orientation, sections 70 and 72 being oriented with the commissures 27,28 and longitudinal attachment

struts 49,50 carrying the valve structure 12 being oriented proximally toward the first end 13 of the prosthesis 10. The repeating, uniform design of the support structure 11 of the illustrative embodiment advantageously provides better structural stability, compressibility/expandability, and overall integrity than a support structure that does that comprise a non-uniform, non-repeating frame pattern.

Page 22, paragraph beginning on line 28, amend to read:

-- FIG. 18 depicts an embodiment having generally, but not absolutely parallel longitudinal attachment struts 49,50 which slightly converge toward the distal end 14 of the prosthesis 10 (and are spaced more distant from each other than the embodiment of FIGs. 13-14. The commissural bends 27,28 and distal bends 82 interconnect the longitudinal attachment struts and form a closed cell 92 as in the embodiment of FIGs. 13-16. The distal attachment struts 51,52 provide the interconnection between the opposite closed cells 92 as well as the distal portion 76 of the attachment pathway 74. They also carry a lateral arm ~~93~~ 94 and together comprise the lateral support structure ~~83,84~~ 53,54 that provide longitudinal support/stabilization and leaflet protection. The embodiment of FIG. 18 lacks proximal support arms 77,78 of the embodiment of FIGs. 13-16.

Page 23, paragraph beginning on line 18, amend to read:

-- The illustrative support structure 11 in FIGs. 9, 11, 13-18 is not critical to achieve the optimal leaflet angles in the valve structure 12 for creating larger pockets, as depicted. For example, the attachment pathway 74 of the valve structure 12 can comprise an attachment to an outside support frame to form the illustrative configuration with the frame 32 that is not necessarily extending along the outer edges 39 of the leaflets 60,61, but rather attached to selected strut that cross the attachment pathway 74, especially along the distal portion 76 of the pathway. Furthermore, at least a portion of the outer edges 39 can be directly affixed to the vessel wall (such as being sutured, heat welded, or anchored with barbs, adhesives, etc.) with the frame 11 being absent or reinforcing or shaping only a limited portion of the leaflet outer edges 39, thus allowing for the vein to naturally collapse (at least partially) when not filled with blood. In the example depicted in FIG. 21, the frame 11 comprises a partial support 98 of a hair-pin configuration that includes a proximal bend about each commissure 27,28 with free-ended longitudinal attachment struts 49,50 extending therefrom which help

form the leaflet angle 47, while the distal portion 76 of the attachment pathway 74 comprises an alternative attachment that does not result in the leaflet material being urged thereagainst by a radially expandable frame. Methods include surgical attachment, tissue welding, adhesives, barbs and other well-known methods, teachings of which is included in a co-pending U.S. Patent Application entitled, 'Percutaneously Deployed Vascular Valves' with ~~Wall-Adherent Adaptations (Case et al.)~~ filed April 1, 2004 (Ser. No. ~~to be added by amendment~~ PCTUS04/09971), the disclosure of which is expressly incorporated by reference herein. The angle of the leaflets 60,61 relative to the longitudinal axis 64 of the prosthesis and vessel (half of the first angle 47 or $\alpha/2$) is preferably -5-15° with a more preferred angle of 0-10° and a most preferred angle of 0-5°. The relatively small or shallow angles of the longitudinal attachment struts 49,50 about the commissures 27,28 allows for a larger space adjacent the leaflets 60,61 and broader pockets 35 at the base of the leaflets. The longitudinal attachment struts 49,50 of the support structure can be formed generally parallel to one another along the proximal portions of the longitudinal attachment struts 49,50 to create the maximum pocket size and greater coaptation of the leaflets. For example, the pocket 35 areas would be maximized in an attachment pathway 74 where angle 47 is zero (or a negative angle) and angle 48 is at least 90°, such that the attachment pathway along each leaflet lateral outer edge 87,88 is generally L-shaped such that the distal portion 76 of the attachment pathway angles abruptly from the proximal portion rather than assuming a dog-leg configuration as shown in the illustrative embodiments.